E 510(k) Summary

Submitter's Name:	MiraMedica, Inc.
Submitter's Address:	15466 Los Gatos Blvd., Suite 109-171, Los Gatos, CA, 95032
Submitter's Telephone:	(408) 858-0718
Contact Name:	Wido Menhardt
Date Summary was Prepared:	April 04, 2003
Trade or Proprietary Name:	Consultiva™ Case Input Station
Common or Usual Name:	System, Image Processing, Radiological
Classification Name:	Picture Archiving and Communications System (21 CFR 892. 2050)

Predicate Devices:

Device Name	510(k) Number
ExpressSuite	K011049
ImagClear	K992467
IMPAX Workstations	K022292

Description of the Device and Summary of the Technological Characteristics:

The Consultiva™ Case Input Station (CIS) is a Windows-based program that facilitates the digitization of medical images and saves these digital images to a specified location on hard disk. Although the CIS is a stand-alone system, it requires a digitizer to get data. The CIS interfaces with the digitizer through high level programming interfaces that allow the CIS to initiate scans and receive messages from the digitizer. The CIS provides a User Interface (UI) that allows the user to initiate scans and verify the completion of the scans (visually) as well as view error information.

The CIS can operate as a stand-alone system to collect medical images. It can also be the first step in a larger medical system. It interfaces with downstream products by sending and receiving messages. If configured in this mode, the CIS can display status information (e.g. Pass of Fail) to the user through the UI.

The CIS also provides some Quality Control (QC) procedures to verify digitizer performance. These procedures are initiated from the CIS UI and require specific test films to be digitized and processed. In the regular workflow, the CIS also implements some quality checks on each image to ensure that the image is of sufficient quality.

Indications for Use:

The Consultiva™ Case Input Station is a software application that facilitates the digitization of medical images from a commercial digitizer and archives the digital images. The Consultiva™ Case Input Station is intended for use by a technician under the supervision of a medical professional.

Substantial Equivalence:

The Consultiva™ Case Input Station is similar to predicate devices such as the VIDAR ExpressSuite, Agfa IMPAX Workstation, and the Titan (formerly DBA) ImagClear. The intended use for the CIS and the predicate devices is for the digital acquisition and archiving of medical images. All of the devices operate on commercially available computer systems such as a Windows-based system and all interface with commercially available digitizers.

Testing:

Various tests of the software to verify system specifications are being performed. Verification procedures with pass/fail criteria were developed to ensure that the product met all the specified requirements.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 26 2003

Wido Menhardt, Ph.D.
General Manager, CAD Business Segment
Eastman Kodak Company
100 Centry Center Court, Suite 600
SAN JOSE CA 95112

Re: K031132
Trade/Device Name: Consultiva™ Case Input Station
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communication system
Regulatory Class: II
Product Code: 90 LLZ
Dated: October 27, 2003
Received: October 30, 2003

Dear Dr. Menhardt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

D Indications for Use Statement

Ver/ 3 – 4/24/96

Applicant: MiraMedica, Inc.

510(k) Number (if known): K031132

Device Name: Consultiva™ Case Input Station

Indications For Use:

The Consultiva™ Case Input Station is a software application that facilitates the digitization of medical images from a commercial digitizer and archives the digital images. The Consultiva™ Case Input Station is intended for use by a technician under the supervision of a medical professional.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K031132

Prescription Use ✓
per 21 CFR 801.109

Over the Counter Use _____